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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,534	03/28/2002	Ubaldo Armato	17642-59	5010

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EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,534

Applicant(s)

ARMATO ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/28/02</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims examined on the merits are 1-15, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 4-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for fibroin as required by claim 3, does not reasonably provide enablement for any other fibroin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification fails to provide an enabling description for fibroin other than fibroin secreted by the *Bombyx mori* silkworm as required by claim 3. No other specific fibroin is described. The claims must be commensurate in scope with the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear as to the substrate required
10 by defining the substrate in terms of highly functional language of how the substrate functions in use and requiring only fibroin as a specific component.

In the last two lines of claim 1, it is uncertain as to what would be a mixture and/or combination including fibroin since the
15 description and examples in the present specification fail to disclose mixing anything with fibroin when preparing a fibrin membrane. See pages 30, 35 and 36 where fibroin membranes are prepared without mixing or combining fibroin with any other component.

Claim 4 is unclear as to fibroin that is of synthetic origin.
20 The specification fails to define fibroin of synthetic origin and describe how such fibroin is obtained.

In claims 5 and 11, it is unclear as to purity of fibrin that is pure fibroin, and it is uncertain as to fibroin that is pure and not pure. The specification fails to define pure fibroin and define a
25 line of demarcation between pure and non-pure fibroin.

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In claim 6, the meaning and scope of fibroin derivatives is uncertain since the specification fails to define fibroin derivatives and describe how such derivatives are obtained.

Claim 7 is confusing and unclear by claiming numerous
5 alternatives by reciting "and/or" twice and then reciting "any of their combinations". This appears to be duplicative.

Claims 13 and 14 is confusing and unclear by requiring use without setting forth process steps for a complete process of using the substrate.

10 Claim 15 is confusing and unclear by not setting forth clear, distinct and positive process steps.

Claims 7-10 and 12-15 are confusing and unclear and improper dependent claims by being multiple dependent and depending on another multiple dependent claim.

15 ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

20 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

25 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(a or b,
respectively) as being anticipated by Santin et al or Gotoh et al
30 (both listed on form PTO-1449 of 3/28/02).

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The claims are drawn to a substrate to be used as an artificial transplanted tissue comprising fibroin.

Santin et al and Gotoh et al disclose preparing a fibroin film in the same way as described in the present specification when preparing a fibroin membrane. The film adheres cells, and the fibroin film is formed on synthetic polymer plate or film. See Santin et al (page 383 under "Sample preparation"), and Gotoh et al (page 352, under "Preparation of aqueous solutions of NSF and RSF" and "Preparation of SF matrices for cell culture experiments". The plate or film is a scaffold as in dependent claim 8. The fibroin film of Santin et al and Gotoh et al is inherently capable of functioning as presently claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of

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each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5 Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cappello (5,606,019) or Tsubouchi et al (6,440,740 B1) or Tsubouchi (6,175,053 B1) in view of Santin et al and Gotoh et al.

 The invention, Santin et al and Gotoh et al are described above.

10 Cappello discloses preparing implantable devices from fibroin and elastin (col 15).

 Tsubouchi et al discloses preparing a wound coating containing fibroin and a polyamino acid (col 8, lines 30-45).

15 Tsubouchi discloses preparing a wound dressing containing fibroin and sericin (col 2, lines 46-54).

 It would have been obvious to use as the fibroin of Cappello, Tsubouchi et al or Tsubouchi, fibroin produced as disclosed by Santin et al and Gotoh et al. This would have resulted in a substrate as presently claimed. The conditions of dependent claims would have been
20 obvious from the conditions used by the references.

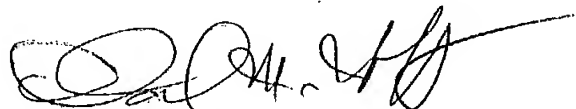
Conclusion

 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be
25 reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

5 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For
10 more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

15 DMN
9/30/04